

Remarks

Rejection Under 35 U.S.C. § 102

Claims 10, 11, 13 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Valentin, et al., *Appl. Microbiol. Biotechnol.* 36:507-514 (1992) (“Valentin”) or Lee, et al., *Appl. Microbiol. Biotechnol.* 42:901-909 (1995) (“Lee”). Applicants respectfully traverse this rejection.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and **every** element of the claims. *Hybritech Inc v Monoclonal Antibodies Inc*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987); *Scripps Clinic & Research Found v Genentech Inc*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 USPQ2d at 1010:

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps, Id.*:

[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove

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facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

Valentin

Valentin discloses formation of **terpolyesters** containing 4-hydroxyvalerate (4HV), 3-hydroxybutyrate (3-HB) and 3-hydroxyvalerate (3-HV). Valentin does not disclose or suggest methods for forming homopolymers of poly(4HV). Valentin at page 513, first full paragraph under the heading "Discussion" states that "[i]n this study the formation of a new biosynthetic terpolyester consisting of 4HV in addition to 3HB and 3HV, which were the only other constituents detected, has been described." Therefore, Valentin does not describe forming homopolymers of poly(4HV) nor poly(3HB-4HV) co-polymers. The Examiner states that Table 2 indicates formation of poly(4HV). Table 2 is discussed in Valentin at page 510 under the heading "*Accumulation of PHA containing 4HV.*" Valentin states that "...in the presence of an excess of 4HV as sole carbon source...appreciable amounts of a **terpolyester** (Fig. 1), consisting of 3HV...and 3HB...and 4HV" was accumulated. Figure 1 shows the structure of the poly(3HV-*co*-3HB-*co*-4HV) terpolyester. This is clearly not a homopolymer of poly(4HV) nor a copolymer of poly(3HB-4HV). The Examiner's statement that "the accumulated polymer is considered a poly(4-hydroxyvalerate) due to the presence of these numerous 4-hydroxyvalerate" is incorrect. A homopolymer of 4-hydroxyvalerate contains **only 4-hydroxyvalerate** monomers. The polymers described in Valentin are not homopolymers of 4-hydroxyvalerate nor copolymers

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of 3-hydroxybutyrate and 4-hydroxyvalerate as defined in claim 10. In addition, Valentin does not disclose or suggest expressing one or more heterologous genes encoding the enzymes as required by claim 11. Therefore, Valentin does not anticipate claims 10, 11, 13 and 18.

Lee

Lee does not disclose or suggest formation of the homopolymer poly(4-hydroxyvalerate). Lee at page 905, the first full paragraph, clearly states that “[w]hen...4-hydroxyvaleric acid was provided as [the] sole carbon source, their incorporation into the accumulated polymers **did not occur**...Only *Pseudomonas* sp. A33 synthesized a **tercopolyester** of 3HB, 3HV **and** trace amounts of 4-hydroxyvaleric acid **(Table 3)**.” Therefore, Lee discloses formation of tercopolyesters **not** homopolymers of poly(4-hydroxyvalerate) or copolymers of poly(3HB-4HV). In addition, Lee does not disclose or suggest expressing one or more heterologous genes encoding the enzymes as required by claim 11. Therefore, Lee does not anticipate claims 10, 11, 13 and 18.

U.S.S.N. 10/600,480

Filed: June 20, 2003

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Allowance of claims 10, 11 and 13-19 is respectfully solicited. If the Examiner still believes that the claims are anticipated by Valentin or Lee, the undersigned respectfully requests an interview with the Examiner.

Respectfully submitted,

/Patrea L. Pabst/

Patrea L. Pabst

Reg. No. 31,284

Date: April 28, 2006

PABST PATENT GROUP LLP

400 Colony Square, Suite 1200

1201 Peachtree Street

Atlanta, Georgia 30361

(404) 879-2151

(404) 879-2160 (Facsimile)